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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,536	08/25/2003	Robert Owen Lockerbie	B0175-US02	4649

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EXAMINER	
LEE, JAE W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,536	LOCKERBIE ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-15,17-19 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15,17-19 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status - Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/17/2010 has been entered.

Claims 12-15, 17-19 and 22 are pending.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15, 17-19 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodrich et al.[1] (USPN 6,258,577) in view of Joshi PC (Comparison of the DNA-damaging property of photosensitised riboflavin via singlet oxygen (1O2) and superoxide radical O2-. Mechanisms, Toxicol Lett. 1985, 26(2-3):211-7). It is noted

by the Examiner that the instant rejection was recited in the previous Final Office action mailed on 12/18/2009.

Applicant's Response and Examiner's Rebuttal:

Applicants argue that there is no disclosure in Goodrich of using riboflavin and light (at any wavelength) to inactivate white blood cells. Column 4, line 5 of Goodrich lists the microorganisms that may be treated with riboflavin and light. Viruses, bacteria, fungi and protozoa are listed. White blood cells are not. Therefore, there is also no disclosure of using riboflavin and light to cause damage to the nucleic acids of white blood cells and substantially maintaining the damage to the nucleic acids of white blood cells as Applicants' claim. Thirdly, and as the Examiner admits, Goodrich does not disclose the specific use of UVB light to inactivate white blood cells. Combining the teachings of Goodrich with the teachings of Joshi, one skilled in the art would think that irradiating blood products with riboflavin and UVB light would produce activated oxygen species which would cause damage to the red blood cells, platelets and plasma being irradiated, and cause tumor promotion and cancer in the irradiated cells. Furthermore, as neither Goodrich nor Joshi teach the irradiation of white blood cells with UVB light, one skilled in the art would not think to do this using the combined teachings of Goodrich and Joshi. Furthermore, Applicants allege that the Examiner has not provided an objective reason to combine the teachings of the references. The mere statement that one skilled in the art would have been motivated to combine the references is not enough to establish a prima facie case. The Examiner argues that "it would have been obvious to a skilled artisan to characterize the dose-response relationship for the

inactivation of white blood cells in order to determine the minimum dose of UVB required for inactivating riboflavin which results in the inactivation of white blood cells" and points to Examples 5 and 6 for support of his position. However, Example 5 studies the extent to which UV light without riboflavin can penetrate a red blood cell sample. Measuring the depth of UV light penetration into red blood cells is not "characterization of the dose-response relationship for irradiating cells with UV light in the presence of riboflavin" as stated by the Examiner. Firstly, Example 5 does not measure the effect of riboflavin and UV light, as there is no riboflavin present. Secondly, Example 5 does not measure the damage to red blood cells caused by riboflavin and UV light. The definition of penetration is "to pierce or pass into or through" (Random House Webster's Unabridged Dictionary). Example 5 measures the distance into a red blood cell sample UV light can pass into. This is not measuring the effect of riboflavin and UV light on cell damage. Example 6 does indirectly study the effect of riboflavin and UV light on platelets by measuring in vitro measurements of platelet function. However, platelets are not white blood cells. Platelets do not have nucleic acids and therefore the nucleic acids can't be damaged by riboflavin and light. Combining the teachings of Ex. 5 and 6 would teach one skilled in the art to measure the distance UV light is able to penetrate into a sample containing red blood cells or platelets. It would not teach them to inactivate the nucleic acids of white blood cells.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Contrary to Applicants' allegation that Goodrich et al. do not teach irradiating white blood cells, as stated in the previous office actions,

Goodrich et al. teach irradiating UV light to *"whole blood" or "blood constituents" or "separated blood products", "bacteria" and/or "virus"* which one of skill in the art would interpret to be *inclusive of red blood cells, white blood cells, platelets, plasma, bacteria and/or virus* in the presence of riboflavin acting as a photosensitizer (see Claims 1, 7-10 and 16-18 in columns 23-24), which meet the limitations of Claims 12-15, 17-19 and 22 with the exception of using UVB. Joshi teaches that riboflavin can be activated by exposing to UV-A (320-400 nm) and UV-B (290-320 nm) light. As such, one of ordinary skill in the art would have been motivated to use the methods taught by Goodrich et al. and Joshi in order to inactivate [1] donor white blood cells which can cause a series of severe immune responses in a transfusion recipient (as evidenced in Lee et al., From leukocyte reduction to leukocyte transfusion: the immunological effects of transfused leukocytes, Bailliere's Clinical Haematology, Vol. 13, No. 4, pp: 585-600, 2000), and [2] bacteria, viruses, and parasites which are potential sources of infection that have been transmitted by allogeneic transfusions. It is emphasized by the Examiner that in an obviousness-type rejection a single reference does not have to teach all the elements of the claims as long as the combined teachings of the prior art references meet the limitations of the claims. In this case, there is a clear motivation for combining the references of Goodrich et al. and Joshi as explained herein and in the previous office action.

Furthermore, it would have been obvious for one of skill in the art NOT to irradiate blood products, such as red blood cells and platelets, with an extreme concentration/dose of riboflavin and UVB light so that the irradiated cells become

cancerous because a skilled artisan would have known the effect of extreme exposure to UVB light, and would have characterized the dose-response relationship of the amount of UVB irradiation cells are receiving and its effect (inactivation versus carcinogenesis). Even assuming *arguendo* that the method of characterizing dose-response relationship of the amount of UVB irradiation cells are receiving and its effect is not taught by the Examples 5 and 6 of Goodrich et al., the reference of Meunier et al. (Photogenotoxicity of mammalian cells: A review of the different assays for In Vitro testing, Photochemistry and Photobiology, May 2002, pg. 1-17, see NPL provided with the Office action on 10/18/2007) teaches that assays for measuring cytotoxicity, apoptosis, or genotoxicity of mammalian cells from the UVB irradiation were routinely practiced in the prior art (see pages 2-8). Therefore, it would have been obvious to a skilled artisan to characterize the dose-response relationship for the inactivation of white blood cells in order to determine the minimum dose of UVB required for activating riboflavin which results in the inactivation of white blood cells. As evidenced in the references of Meunier et al. and Goodrich et al., the characterization of the dose-response relationship for irradiating cells with UV light in the presence of riboflavin was routine in the prior art with a finite number of predictable outcomes. Therefore, for the reasons described herein and in the previous office action, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Conclusion

Claims 12-15, 17-19 and 22 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on M-F between 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656